

## PIH56

## MEASURING QUALITY OF LIFE IN FACIAL AESTHETIC PATIENTS: FIELD-TESTING OF A NEW MODULAR SYSTEM (THE FACE-Q)

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**OBJECTIVES:** In aesthetic surgery, the assessment of patient-reported outcomes is especially pertinent to clinicians because patient satisfaction and improved quality of life are the predominant considerations determining success. In order to appropriately measure the impact of these procedures, well-developed and validated questionnaires are needed. The objective of this study was to develop a new patient-reported outcome (PRO) measure to evaluate patient satisfaction and quality of life following facial cosmetic procedures (surgical and non-surgical). The main scale: 'Satisfaction with face overall' will be presented. **METHODS:** Field-testing was performed at 3 centers (US and Canada). Preoperative patients were > 18 years and scheduled to undergo a facial cosmetic procedure. Postoperative patients had undergone a facial cosmetic procedure within 2 weeks-5 years. Patients received a questionnaire with standard incentives and reminders. Rasch analysis was used for item reduction and scale development (RUMM2030®), each scale and item were examined according to 7 measurement criteria (clinical meaning, thresholds for item response options, item fit, item locations, DIF, standardized residuals, person separation index). **RESULTS:** A total of 344 facial cosmetic patients (pre procedure n=79, post procedure n=265) participated. Scales were constructed for each area defined as important to patients by the qualitative data. This was achieved by choosing sets of items hypothesized to constitute a scale, analyzing the data against measurement criteria and making decisions on item selection and deletion. The main scale 'Satisfaction with Face Overall' fulfilled Rasch and traditional psychometric criteria (including Person Separation index 0.94; Cronbach's alpha 0.95). **CONCLUSIONS:** The FACE-Q is a new PRO measure that will provide essential information about the impact and effectiveness of surgical and non-surgical facial aesthetic procedures from the patients' perspective. It is conceptually grounded in patient perceptions and fulfills criteria for rigorous measurement. It will support multi-center studies, while also being clinically useful.

## PIH57

## APPLICATION OF THE BOTHER CONCEPT ACROSS CULTURES

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**OBJECTIVES:** The objective of this study was to analyze the concept of *bother* as it is used in translated Patient Reported Outcomes (PRO) instruments. In American English, *bother* is versatile as it may connote negative mental, physical, and social conditions. Because of this versatility, the concept may have different meanings across languages and cultures. In observing the term *bother* in PRO instruments, it will be determined whether the concept remains equivalent when translated. **METHODS:** To determine the meaning of *bother* across many languages, linguists, cognitive debriefing interviewers, and cognitive debriefing subjects were asked to complete a questionnaire following the linguistic validation of a psoriasis PRO instrument which contained *bother* as the key concept. Furthermore, all instances of *bother* as it appeared in back-translated instruments and cognitive debriefing reports were analyzed. **RESULTS:** By analyzing questionnaires completed by respondents, we identified many instances where *bother* was described as an ambiguous concept. An analysis of back-translations showed that the term was changed 55% of the time and the concept was back-translated as something conceptually different 20% of the time. During cognitive debriefing, 16% of subjects paraphrased *bother* incorrectly, while several suggested the removal or replacement of *bother*. **CONCLUSIONS:** When developing PRO instruments, consideration should be given to the equivalency of key concepts across different languages and cultures if they are to be useful in multinational clinical trials. In this study we discovered that while respondents understood *bother* to have a negative connotation, data across languages shows a lack of conceptual equivalency. As a result, *bother* may not be the most ideal measurement of disease symptom severity and quality of life. Therefore, in the development of PRO instruments, ambiguous concepts such as *bother* ought to be replaced with more specific concepts to measure many components of one's quality of life.

## PIH58

## MOBILE PHONE USE IN PATIENT REPORTED OUTCOMES - ACADEMIA AND BEYOND

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**OBJECTIVES:** To demonstrate that mobile phones can be used to collect patient reported outcomes. **METHODS:** A literature search was conducted looking at articles published between 2009 and 2011 that referenced electronic diaries of some description. These were then filtered to pull out those that referenced mobile or cellular phones. **RESULTS:** Ninety articles were found that reference electronic diaries specifically. Out of these, 8 articles specifically referenced mobile/cellular phones. The studies referenced in these articles were carried out on populations with an age range of 9 years up to 70 (reported mean 21.8; SD - TBD). The studies were split into 6 therapy areas; physical activity, weight management, sexual activity, asthma, alcohol related and pain, and all but one of the studies included both males and females, with the other being female only. Population size ranged from 15 to 994 (mean 249.8; SD-TBD), in the USA, Europe, Australasia and Asia, and subjects reported for a minimum of 7 days (but up to 6 reports per day) to a maximum of 365 days (mean 110.4 days; SD-TBD). Pain data were only collected in one study; momentary reporting occurred in half of the studies and subject preferences

were collected in three studies. Compliance was reported to have been collected in four of the studies and 3 studies reported giving the subjects training. Notably, 5 out of the 8 studies allowed the subjects to use their own mobile phone for the reporting. **CONCLUSIONS:** All of the articles concluded that mobile phones were suited to collect data from subjects, especially momentary reporting. It was noted that the use of mobiles was acceptable to the populations as they used them in everyday life and found then to be convenient, and the researchers found the technology to be inexpensive to implement.

## PIH59

## PATIENT-REPORTED OUTCOMES: THE GROUNDED ITEM TECHNIQUE FOR GENERATING CONTENT VALID QUESTIONS

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**OBJECTIVES:** Qualitative research methods have become increasingly important to Patient Reported Outcome (PRO) measure developers since the emphasis on content validity in the Food and Drug Administration's guidance for the development of PROs. The Critical Incident Technique (CIT) is a rigorous data collection protocol to provide empirically-derived data on human behavior. More than 130 research studies employing the CIT have been published in the medical and health services research literature alone (according to PubMed indexing for 2002-2011). We describe here our work building on the CIT to develop a rigorous method for generating content-valid items for patient-reported measures which we call the Grounded Item Technique. **METHODS:** The CIT was not developed to generate items. Its most common use is to develop conceptual frameworks or taxonomies in conjunction with Grounded Theory (Glaser & Strauss, 1967) data analysis. By contrast, the Grounded Item Technique (GIT) is specifically focused on item generation. We developed a five-phase process for the GIT including the development of the interview protocol, conduct of interviews, abstraction of incidents from interviews, abstraction of items from incidents, and documentation of content validity. In this presentation we detail that process and illustrate it using two case studies from our actual measure development projects. **RESULTS:** We were able to use the GIT procedure to fill important gaps in the measurement provided by an established tool while at the same time supporting the content validity of that tool. We successfully applied the GIT to generate content-valid PRO items for a rare condition affecting an underserved population. Field testing showed these items to be highly sensitive to health differences. **CONCLUSIONS:** These case studies suggest that we have successfully adapted the CIT protocol for use in generating content-valid patient-reported health items. With this presentation, we hope to stimulate other investigators to use the Grounded Item Technique in PRO-item generation.

## PIH60

## SPEAKING OF PROS: TOWARDS FINDING A COMMON PROSE FOR IMPROVING COMMUNICATION ABOUT HEALTH-RELATED QUALITY OF LIFE CONCEPTS

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**OBJECTIVES:** The lack of a common terminology for naming concepts at the family and sub-family levels has increased the reluctance of various stakeholders to accept the use of PROs for decision-making, such as in an FDA label claim. This research examines the conceptual content of selected PRO instruments, identifies similarities and differences across instruments, and explores the extent to which the availability of a classification system or taxonomy of concepts might bring standardization to the field and thus improve communication. **METHODS:** The structure and conceptual content of items in existing instruments is evaluated using a grammar-like decomposition of each item along with the item- or domain-level concept assigned by the instrument developer. Item-level concepts are also assigned a classification code using the WHO International Classification of Functioning, Disability and Health (ICF). This code identifies a concept by its major component, a high-level concept of function, disability, or environmental factors, and by its lower-levels, as appropriate. **RESULTS:** Approximately 650 items from 25 disease-specific and generic instruments were evaluated according to the grammar and the ICF. Grouping the items by ICF codes indicated a wider range of concept names assigned by the developers than by the classification system. For example, the 21 items classifiable in the Ingestion Functions of the ICF Functions Related to the Digestive System Category were assigned either to this group level or to three sub-level categories. The instrument developers assigned these same 21 items to 7 different concepts. This same pattern of greater diversity of concepts assigned by developers than by the ICF was observed for other WHO categories. **CONCLUSIONS:** Instrument developers assigned diverse concept names to represent items that assess similar areas of functioning. The analysis suggests directions for future development of a taxonomy appropriate for classifying health-related concepts used for making statements about treatment benefit.

## PIH61

## BURDEN OF DISEASE IN PATIENTS WITH MENOPAUSE IN BRAZIL: RESULTS FROM 2011 NATIONAL HEALTH AND WELLNESS SURVEY (NHWS)

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**OBJECTIVES:** Brazil is said to be the fifth most populous nation worldwide, with slightly more than one-half of Brazilian adults being women. The number of women experiencing menopause is expected to rise as population of Brazil ages and people live longer. This study is aimed to assess co-morbidity, quality of life (QOL), work/productivity loss, and medical resource utilization in patients with